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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,065	05/05/2005	Hector F Deluca	1256-01012	1544

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ANDRUS, SCEALES, STARKE & SAWALL, LLP
100 EAST WISCONSIN AVENUE, SUITE 1100
MILWAUKEE, WI 53202

EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,065	DELUCA ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8-22 and 29-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8-22 and 29-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 09/16/2008. Claim(s) 1, 8-22 and 29-45 are pending. Claim(s) 1 and 29 have been amended. Claim(s) 33-45 have been added. Claim(s) 1, 8-22 and 29-45 are examined herein.

Response to Arguments

Applicants arguments against the ODP rejection over Application 10/105,826 is not persuasive because Applicant is now arguing based on amended claims, but in view of Applicant's amendments to the claims a modified ODP rejection is now made.

Applicant's arguments with respect to the 103(a) obviousness rejection of claims 1, 8-22 and 29-32 as being unpatentable over DeLuca (U.S. Patent No. 5,843,928) in view of DeLuca (WO 97/11053) and Bockman et al. (US Patent No. 5,556,645) have been fully considered but found not persuasive as Applicant is now arguing based on amended claims. Since Applicant has amended the claims, said rejection is hereby withdrawn.

Applicants argue that there is not a teaching, suggestion, or motivation in the cited references to administer the 2-carbon-modified vitamin D compounds for the recited purposes (i.e., stimulating growth of new periodontal bone or osteointegration of a dental implant).

This is not found persuasive because Deluca et al. (US) teach that the compound, 2MD is useful for the treatment of disease in human where bone formation is desired. Therefore, this teaching would immediate prompt one of ordinary skill in the art to employ 2MD for the stimulation of new bone including growing new bone at the site of a fracture as well as growth of any kind of bone. The fact that Applicant has limited it to periodontal bone or dental implants is not persuasive.

The office action below sets forth the following rejections as necessitated by amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8-22 and 29-45 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1, 8- 10, 20, and 29-38 of copending Application No. 10/105826.

The instant claims are directed to a method of stimulating growth of new periodontal bone and stimulating osteointegration of dental implant.

Claims of copending application are directed to a method of increasing the rate of repair for a bone fracture by stimulating osteoblast cells to form new bone comprising administering to a subject in need thereof an effective amount of a compound in an immobilized, slow release form at the bone fracture, said compound having the formula I.

The difference between the instant claims and the claims of the copending application is stimulating growth of new versus increasing the rate of repair for a bone fracture.

The instant applications are overlapping in scope because by increasing the rate of repair of a bone fracture, one is in fact stimulating the growth of new bone at the site of the fracture. The fact the Applicant has limited the type of bone to periodontal is not relevant because growing new bone is growing new bone, no matter where the site.

As such, the claims of the instant Application and the patented claims would have been obvious variations of the other to one of ordinary skill in the art because both set of claims are directed to stimulating growth of new bone.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-11 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (U.S.Patent No. 5,843,928) hereinafter "Deluca (US)".

Deluca et al. (US) teach the compound, 2-carbon-modified vitamin D (2MD) is useful for the treatment of diseases in human where bone formation is desired and the compound is also suited for treatment and prophylaxis of human disorders such as host versus graft reaction, and rejection of transplants, as well as improvement of bone

fracture healing and improved bone grafts (abstract, columns 3 and 4, particularly column 4, lines 20, 30- 39). Deluca et al. teach the treatment may be transdermal, oral or parenteral in an amount from about 0.1μg/gm to about 50μg/gm of the composition and may be administered in dosages of from about 0.1μg/day to about 50μg/day (column 4, lines 15-30). Deluca et al. teach 2MD can be formulated conveniently by any of the method well known in the art of pharmacy (column 18, lines 50-60).

Deluca et al. (US) do not specifically teach employing the 2MD compounds to stimulate the growth of new periodontal bone.

It would have been obvious to one of ordinary skill in the art at the time the invention to employ 2MD for treating individuals where bone formation is desired and also used the instant compound as a method of stimulation growth of new periodontal bone. As taught by Deluca (US), the ultimate objective is to form bone where desired, thus by stimulating growth of periodontal ultimately leads to the formation of new bone. Deluca (US) does not limit the location of desired bone formation, thus it would have been obvious that one could employ the administration of the compounds for the formation of periodontal bone.

Claims 29, 30, 33-35, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (U.S.Patent No. 5,843,928) of record hereinafter "Deluca (US)", as applied to claims 1, 8-11 and 20-22 above in view of Deluca et al. (WO 02/05823A2) of record hereinafter "Deluca (WO)", and Bockman et al. (U.S.Patent No. 5,556,645) of record.

Deluca et al. (US) is discussed above.

Deluca et al. (US) do not teach stimulating osteointegration of dental implants.

Deluca et al. (WO) teach that 2MD stimulates the osteoblasts at least 80 times more potent than 1, 25 $(OH)_2D_2$ (pages 9-10, under INTERPRETATION OF DATA). Deluca et al. (WO) teach that 2MD can be use in hip and knee replacement surgery (abstract).

Furthermore, Deluca et al. (WO) teach that this compound increases breaking strength as well as crushing strength and thus could be also used in conjunction with bone replacement procedures such as hip replacements, knee replacements, and the like (page 5, lines 3-7).

Bockman et al. teach that bone is formed by matrix-producing cells known as osteoblasts. Bockman et al. teach that osteoblast is responsible regulating the rate of formation and the architecture of newly formed bone (column 3, lines 31-57). Bockman et al. teach that compounds enhancing bone formation are suitable for use in the field of bone implants including both bone grafts and prosthetic devices. Bockman et al. teach that implants are routinely used to replace damaged or diseased joints and to support or replace weakened or lost bone. Bockman et al. teach that the implant can be used with a polymer that allows slow diffusion of the compounds that enhances bone growth for a suitable period of time (column 7, lines 50-60, column 8, lines 5-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the 2MD compounds as taught by Deluca (US) and also employed them to stimulate osteointegration of an implant. The motivation, provided by

Deluca (WO) teaches that the 2MD compounds can be administered to enhance bone formation with bone replacement procedures. Since dental implants are a type of bone replacement, then one in the art would expect, with a reasonable degree of success, that the compounds would be effective in stimulating osteointegration. As further taught by Brockman, implants are employed to replace damaged or diseased joints or to support lost or weak bone, thus dental implants would also be an obvious choice to form new bone.

Claims 12-19 and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deluca (U.S. Patent No. 5,843,928), hereinafter "Deluca (US)", as applied to claims 1, 8-11 and 20-22 above in view of Deluca (WO 97/11053), hereinafter "Deluca (WO)".

Deluca (US) is discussed above. Deluca (US) teaches that Y1, Y2, and R5 can be hydroxyl protected (page 4, lines 11-12).

Deluca (US) does not explicitly teach that the protecting groups are acyl esters.

Deluca (WO) teaches that among the modified vitamin D compounds, which may be used where bone formation is desired, having a desirable in vivo bioactivity profile, an especially important and preferred class of protecting groups are certain acyl ester derivatives (page 6, lines 26-30). Some specific examples are triacetate, trihexanoate, trinonoate, and acetate, as per claims 12-19 (page 11, line 22-page 12, line 5).

It would have been obvious to one of the ordinary skill in the art at the time of the invention to have protected the compounds taught in Deluca (US) with the protecting groups (e.g. acyl esters) as taught in Deluca (WO). One would be motivated to do so because it is well known in the art that triacetate, trihexanoate, trinonoate, and acetate are acyl protecting esters which are readily hydrolysable and are commonly used in the field.

Conclusion

Claims 1, 8-22 and 29-45 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617